found similar deficiencies, and suspended accreditation of the lab's chemistry and point-of-care departments for 30 days.

To its credit, Maryland General Hospital conducted its own internal review and vigorously undertook efforts both to retest the affected patients and to revamp the lab's leadership and operations.

Fortunately, retesting verified the accuracy of the overwhelming majority of the HIV and Hepatitis C tests. In addition, Maryland General has made enormous strides in improving its lab operations so that patients receive test results that are accurate and reliable.

Nevertheless, Mr. Speaker, this is a situation that caused great distress to the community that Maryland General serves, and I should note that I live in that community and have received care at Maryland General Hospital. This is a situation that could have put many lives in jeopardy and one that simply should never have occurred given the regulatory safeguards that exist to ensure quality testing.

Mr. Speaker, Congress recognized the importance of ensuring that all Americans receive accurate diagnostic test results when it enacted federal standards for medical laboratories under the Clinical Laboratories Improvements Amendments Act of 1998, now known as "CLIA." Under CLIA, the Centers for Medicare and Medicaid Services (CMS) were charged with developing and implementing regulations to ensure that all labs conform to strict federal standards.

Pursuant to CLIA regulations and agreements between CMS and the states, clinical laboratories that choose to be accredited by CAP or one of the five other private accrediting organizations are "deemed" to be in compliance with federal and state regulatory requirements and can bill for services provided to Medicare beneficiaries.

Mr. Speaker, there is no doubting the fact that CLIA has made medical testing more accurate and more reliable and, surely, the overwhelming majority of labs do their best to conform to these high standards. Unfortunately, the Maryland General case clearly demonstrates that not all laboratories will play fair and that the current system does not guarantee that serious instances of noncompliance will be detected or corrected.

Testimony before the Subcommittee indicated that, in the Maryland General Hospital case: laboratory supervisors failed to implement quality control measures and deliberately masked lab deficiencies from inspectors from CAP and the state; employees who complained were subject to retaliation and intimidation; state and CAP inspection teams were unable to identify or verify serious ongoing deficiencies during accreditation and complaint surveys; and enforcement entities failed to share information about reports of deficiencies, investigative actions taken, and their investigative findings.

Since our hearings concluded, another CAP-accredited laboratory in my state, Reference Pathology Services of Maryland, had its CAP accreditation and state license revoked because of longstanding deficiencies related to testing for sexually transmitted diseases and cervical cancer. This case and other information brought to the Subcommittee's attention suggest that at least some of the problems that occurred at Maryland General are not unique to the Maryland General case.

Chairman SOUDER and I have asked the Government Accountability Office (GAO) to examine a number of issues related to the enforcement of federal standards for labs and I expect that investigation to tell us more about the prevalence of such problems.

For now, it is unclear how many other laboratories may be experiencing such problems and, certainly, one would hope the number is few. But the record gives us little assurance that what happened at Maryland General could not occur elsewhere and I believe the Maryland General case reveals weaknesses in the current system for ensuring compliance with federal clinical laboratory standards.

The bill I am introducing today aims to correct the weaknesses that are apparent.

The Clinical Laboratory Compliance Improvement Act of 2004 seeks to improve compliance with laboratory standards by (a) facilitating the disclosure and detection of deficiencies by employees and (b) increasing cooperation and accountability among entities involved in the accreditation and monitoring of federally regulated medical labs.

Specifically, the bill would amend Section 1846 of the Social Security statute to:

(1) Establish whistleblower protections for employees of clinical laboratories and providers;

(2) Require the Centers for Medicare and Medicaid Services, state health agencies, and private laboratory accrediting organizations such as CAP to share information about reports of deficiencies and investigative activity undertaken pursuant to such reports;

(3) Require that standard accreditation surveys be conducted without prior notice to the provider or clinical laboratory facility to be surveyed; and

(4) Require the Secretary of Health and Human Services to submit an annual report to Congress describing how CMS, private accrediting organizations, and state health agencies responded to reports of deficiencies during the preceding year.

The whistleblower provisions would facilitate reporting of deficiencies by: Requiring that participating providers and clinical laboratories post a conspicuous notice advising employees how and to whom to report deficiencies; prohibiting retaliation by providers and clinical laboratories against employees who report deficiencies to CMS, accrediting organizations, or state health agencies; and establishing a federal cause of action for employees who are retaliated against for reporting deficiencies.

With regard to unannounced inspections, the bill sets forth a civil monetary penalty of up to $2,000 for persons who provide notice to a lab or provider about the timing of a survey.

Mr. Speaker, it is sad but true that we cannot afford to take it for granted that all laboratories will approach compliance with laboratory standards in a good faith manner, or even that deficiencies will be discovered when conscientious lab employees want to disclose them.

The Clinical Laboratory Compliance Improvement Act of 2004 would reduce the likelihood that serious laboratory deficiencies will escape the notice of entities charged with ensuring compliance with the standards that we in Congress have established to ensure a high standard of healthcare for all Americans.

I urge my colleagues to join me in demonstrating their support for strengthening our national system for ensuring accuracy and accountability in medical laboratory testing.

I invite my colleagues to cosponsor this important legislation.

Finally, I want to thank my Subcommittee counsel, Tony Haywood, as well as Jolanda Williams, Trudy Perkins and Kimberly Ross of my staff for their tireless work on this issue.

PERSONAL EXPLANATION

HON. ROBERT T. MATSUI

OF CALIFORNIA

IN THE HOUSE OF REPRESENTATIVES

Friday, October 8, 2004

Mr. MATSUI. Mr. Speaker, I was absent on Friday, October 8, 2004, and missed the rollcall votes ordered, due to illness.

PERSONAL EXPLANATION

HON. LOUISE McINTOSH SLAUGHTER

OF NEW YORK

IN THE HOUSE OF REPRESENTATIVES

Friday, October 8, 2004

Ms. SLAUGHTER. Mr. Speaker, I was unable to be present for rollcall votes 494–497, 502, 505, 507–508, 510–512, 517, 518, 520–524, and 526–527. Had I been present, I would have voted "aye" on rollcall votes 495, 496, 497, 502, 505, 507–508, 510, 511, 512, 517, 518, 520, 521, 522, and 527. I would have voted "nay" on rollcall votes 494, 523, 524 and 526. Mr. Speaker, I ask unanimous consent that my statement appear in the permanent RECORD.

CONFERENCE REPORT ON H.R. 4520, AMERICAN JOBS CREATION ACT OF 2004

SPEECH OF

HON. JANICE D. SCHAKOWSKY

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

Thursday, October 7, 2004

Ms. SCHAKOWSKY. Mr. Speaker, I rise today in opposition to H.R. 4520, the so-called American Jobs Creation Act, because it is just another example of the Republicans' seriously misplaced priorities. Instead of closing corporate tax loopholes to fund housing, education, and veterans' programs, the Republicans decided to give 276 new tax breaks in industries from oil and gas corporations to tackle boxes and ceiling fans makers. Instead of encouraging companies to create jobs in the U.S., the Republicans chose to reward companies that export jobs overseas. Instead of helping six million working families make ends meet, the Republicans decided to strip the overtime protections in the Senate bill and erode the 40-hour work week. Instead of regulating tobacco, a drug that kills 400,000 people every year, the Republicans gave tobacco companies a bail out. It seems the Republicans are interested in helping big businesses avoid paying their fair share of taxes and subsidizing the tobacco industry, even if it is at the expense of American workers and families.

The Republicans rammed through those corporate taxes cuts, although corporate taxes are at their lowest level since the 1930s. The